

Claims

11. A pharmaceutical composition comprising a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide wherein, after oral administration thereof to a human, the bioavailability of glibenclamide is comparable to the bioavailability of glibenclamide achieved by oral administration of separate solid oral dosage forms to a human, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form.

12. A pharmaceutical composition comprising a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide wherein, after oral administration thereof to a human, the C_{max} and AUC of glibenclamide are comparable to the C_{max} and AUC of glibenclamide achieved by oral administration of separate solid oral dosage forms to a human, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form.

13. A pharmaceutical composition comprising a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide wherein, after oral administration thereof to a human, the C_{max} and AUC of glibenclamide are + 25% of the C_{max} and AUC, respectively, of the glibenclamide achieved by oral administration to a human of separate solid oral dosage forms, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form.

14. A pharmaceutical composition comprising a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide wherein, after oral administration thereof to a human, the mean C_{max} and mean AUC values of glibenclamide are, respectively, + 25% of 113 ng/ml and + 25% of 842 ng/ml/hr, for a 5mg unit dose of glibenclamide, or proportionally higher or lower values for higher or lower unit doses of glibenclamide, respectively.

15. A pharmaceutical composition comprising a single solid oral dosage form containing an effective dose of metformin and an effective dose glibenclamide wherein, after oral administration thereof to a human, the adjusted geometric mean C_{max} and adjusted

geometric mean AUC values of glibenclamide are, respectively, + 25% of 101 ng/ml and + 25% of 780 ng/ml/hr, for a 5 mg unit dose of glibenclamide, or proportionally higher or lower values for higher or lower unit doses of glibenclamide, respectively.

16. A pharmaceutical composition comprising a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide wherein, after oral administration thereof to a human, the C_{max} and AUC of glibenclamide are comparable to the C_{max} and AUC of glibenclamide achieved by oral administration of separate solid oral dosage forms to a human, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form, the particle size of the glibenclamide in said single dosage form not being such that it alone achieves said comparable bioavailability.

17. A composition of one of claims 11-16 wherein the weight ratio of metformin to glibenclamide is 50/1 to 250/1.

18. A composition of one of claims 11-16 wherein the weight ratio of metformin to glibenclamide is about 100/1.

19. A composition of one of claims 11-16 wherein the weight ratio of metformin to glibenclamide is about 200.

20. A composition of one of claims 11-16 wherein the unit dose of metformin is about 500 mg or about 250 mg.

21. A composition of claim 20 wherein the unit dose of glibenclamide is 5, 2.5 or 1.25 mg.

22. A composition of one of claims 11-16 in the form of a tablet or capsule.

23. A composition of claim 13 wherein said C_{max} and AUC values of glibenclamide in said single solid oral dosage form are + 20% of said C_{max} and AUC values, respectively, of glibenclamide in said separate glibenclamide solid oral dosage form.

24. A composition of claim 13 wherein said C_{max} and AUC values of glibenclamide in said single solid oral dosage form are + 15% of said C_{max} and AUC values, respectively, of glibenclamide in said separate glibenclamide solid oral dosage form.

25. A composition of claim 13 wherein said C_{max} and AUC values of glibenclamide in said single solid oral dosage form are + 10% of said C_{max} and AUC values, respectively, of glibenclamide in said separate glibenclamide solid oral dosage form.

26. A composition of claim 13 wherein said C_{max} and AUC values of glibenclamide in said single solid oral dosage form are + 5% of said C_{max} and AUC values, respectively, of glibenclamide in said separate glibenclamide solid oral dosage form.

27. A composition of one of claims 14 or 15 wherein said C_{max} and AUC values are + 20% of said numerical ranges.

28. A composition of one of claims 14 or 15 wherein said C_{max} and AUC values are + 15% of said numerical ranges.

29. A composition of one of claims 14 or 15 wherein said C_{max} and AUC values are + 10% of said numerical ranges.

30. A composition of one of claims 14 or 15 wherein said C_{max} and AUC values are + 5% of said numerical ranges.

31. A method of treating non-insulin dependent diabetes or hyperglycaemia comprising administering to a patient in need thereof a composition of one of claims 11-16.

32. A method of achieving a bioavailability of glibenclamide in a human upon administering orally a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide, said bioavailability being comparable to the bioavailability of glibenclamide achieved by oral administration of separate solid oral dosage forms to a human, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form, comprising formulating

glibenclamide with metformin in said single solid oral dosage form so as to assure said comparable bioavailability.

33. A method of achieving a bioavailability of glibenclamide in a human upon administering orally a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide, said bioavailability being comparable to the bioavailability of glibenclamide achieved by oral administration of separate solid oral dosage forms to a human, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form, comprising formulating glibenclamide with metformin in said single solid oral dosage form so as to assure said comparable bioavailability, said formulating not being achieved solely by selection of particle size of glibenclamide.

34. A method of increasing bioavailability of glibenclamide in a human upon administering orally a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide, such that said increased bioavailability is comparable to the bioavailability of glibenclamide achieved by oral administration of separate solid oral dosage forms to a human, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form, comprising formulating glibenclamide with metformin in said single solid oral dosage form so as to assure said comparable bioavailability.

35. A method of increasing bioavailability of glibenclamide in a human upon administering orally a single solid oral dosage form containing an effective dose of metformin and an effective dose of glibenclamide, such that said increased bioavailability is comparable to the bioavailability of glibenclamide achieved by oral administration of separate solid oral dosage forms to a human, one containing glibenclamide and the other metformin, in the same respective effective doses as in said single oral dosage form, comprising formulating glibenclamide with metformin in said single solid oral dosage form so as to assure said comparable bioavailability, said formulating not being achieved solely by selection of particle size of glibenclamide.

36. The method of one of claims 33 or 35 wherein said formulating is not achieved by selection of particle size of glibenclamide.

37. A composition of one of claims 11-16 wherein metformin is present as a metformin salt.
38. A method of one of claims 32-35 wherein metformin is present as a metformin salt.
39. A method of claim 31 wherein metformin is present as a metformin salt.
40. A method of claim 36 wherein metformin is present as a metformin salt.
41. A solid oral dosage form of claim 4 in which 50% of particles are less than 25 μm .